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## **Australia**

## **Biotechnology**

## **Agricultural Biotechnology Annual Report**

## 2007

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#### **Report Highlights:**

The United States has substantial interest in Australia's policies and regulatory framework regarding agricultural biotechnology and products derived thereof. Unprocessed (whole) biotech corn and soybeans have not received regulatory approval in Australia and, thus, cannot be imported without further processing. Foods with biotech content of over 1% must receive prior approval and be labeled. This requirement can restrict sales of U.S. intermediate and processed products. Australia's policies and views on this technology influence other countries in the region, and elsewhere, which may follow Australia's lead in developing a regulatory system of their own. The moratoria on new plantings in NSW, Victoria, South Australia, Western Australia, Tasmania and the ACT are all set to expire or are up for review in 2008. The Agriculture Minister has called for states to remove their moratoria.

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Please note: Hyperlinks to various Internet sites are used extensively throughout this report. These links may not be usable in the Adobe Acrobat version of the report so we recommend that users download the Word version to have access to the most detailed and up-to-date information on accessing the Australian market.

#### **Section I: Executive Summary**

The United States has substantial interest in Australia's policies and regulatory framework regarding agricultural biotechnology and products derived thereof. Unprocessed (whole) biotech corn and soybeans have not received regulatory approval in Australia and, thus, cannot be imported without further processing. Foods with biotech content of over 1% must receive prior approval and be labeled. This requirement can restrict sales of U.S. intermediate and processed products. Australia's policies and views on this technology influence other countries in the region, and elsewhere, which may follow Australia's lead in developing a regulatory system of their own.

The biotech debate is very important in Australia. The federal government is very supportive of the technology, has committed considerable long-term funding to research and development, and has approved genetically modified (GM) canola varieties for general release. The State governments have also committed funds for research and development, but most are being more cautious about the introduction of the technology and are using their powers over 'marketing' to restrict biotech crops in their jurisdictions - there are currently moratoria on new plantings of biotech crops in the states of NSW, Victoria, South Australia, Western Australia, Tasmania and the Australian Capital Territory (ACT). Major farm groups and the Commonwealth government's science organizations do not support this position and have argued openly for its acceptance. The moratoria are all set to expire or be reviewed in 2008. Currently in Australia, about 90 percent of the cotton planted is from biotech varieties, which were approved for release prior to the state moratoria.

Australia has a substantial risk assessment based regulatory framework for dealings with gene technology and genetically modified organisms, as well as a process for assessment and approval of genetically modified foods. The Gene Technology Act of 2000 established Australia's regulatory scheme for dealings with gene technology and genetically modified organisms (GMOs). The Commonwealth's Gene Technology Regulator serves the key role in assessing, regulating and licensing GMOs and enforcing license conditions. Genetically modified foods must also be assessed, determined to be safe, and be approved before being sold for human consumption. The standards for such foods are developed by Food Standards Australia New Zealand (FSANZ) and are contained in the Food Standards Code. There are labeling requirements for genetically modified foods containing modified genetic material and/or novel protein, and for foods with altered characteristics. Imports of viable GMOs and food products containing genetically modified ingredients would need to meet these same regulations.

To date, biotech cotton, carnations and canola varieties are the only agricultural crops approved for commercial release into the environment in Australia, while biotech cotton is the only crop grown widely in the country. Research is being conducted on other biotech crops, with field trials controlled by the Office of the Gene Technology Regulator (OGTR) being conducted on some, i.e., rice, white clover, narrow-leafed lupin, grapevines, pineapple, papaya, sugarcane and poppies. Approval has already been granted for food products derived from biotech corn, soybean, sugarbeet, potatoes and oils from biotech cotton and canola (see Appendices II & III).

For GMOs that have not received regulatory approval in Australia, U.S. export opportunities are obviously restricted. For the United States, the commercial impact of this constraint would be most pronounced for feed grain, e.g. whole corn, and soybeans. However, Australia does not allow the importation of many grains and/or grain products for phytosanitary reasons. Furthermore, bans and restrictions on the growing of GMOs in a number of Australian states and territories is slowing the commercialization and adoption of

the technology and negatively impacts the ability of U.S. companies to market their GMO products (specifically canola).

Australia's regulatory framework for genetically modified food and feed has only a relatively limited impact on U.S. exports of these products. Australia requires that food products derived from GMOs, if they contain more than 1% of biotech product, get prior approval from Food Standards Australia New Zealand before they can be sold. Such products must also be labeled to indicate that they contain biotech products.

In addition to Australia's regulatory framework for biotechnology, a government agency – Biotechnology Australia (BA) – coordinates non-regulatory biotechnology issues for the Australian Government. BA, a multi-departmental agency, includes members from the Australian Departments of Industry, Tourism and Resources; Health and Ageing; Agriculture Fisheries and Forestry; Environment Australia; and Education, Science and Training. BA is responsible for developing and implementing Australia's National Biotechnology Strategy (NBS). The NBS supports the Government's vision for biotechnology – capturing the benefits of biotechnology for the Australian community, industry and environment, consistent with safeguarding human health and ensuring environmental protection.

#### **Section II: Biotechnology Trade and Production**

#### **Commercial Crops**

Biotech cotton, color modified carnations and canola are the only crops approved for commercial release by Australia's Gene Technology Regulator. It is estimated that biotech cotton varieties are grown on about 90 percent of Australia's cotton area. The Regulator approved the commercial releases of two biotech canola varieties in 2003. However, commercial plantings of biotech canola are being held up due to moratoriums that have been implemented by state governments in all Australia's major canola producing states. Biotech carnations have recently become the first biotech products to be assessed by the Gene Technology Regulator to "pose minimal risks to people or the environment, and are sufficiently safe to be used by anyone without the need for a license" and they have accordingly been placed on the GMO Register.

#### Biotech Cotton

Biotech cotton has been grown commercially in Australia since the approval and introduction of Bt, or Ingard, cotton in 1996. Roundup Ready cotton (herbicide tolerance) and Roundup Ready/Bt cotton (herbicide tolerance/insect resistance) were subsequently approved and grown commercially for the first time in 2001. In 2003, Australia's Gene Technology Regulator approved an additional cotton variety – 'Bollgard II' – for commercial release and the first major commercial plantings were made during the 2003/04 season. Currently, over 90 percent of the Australian cotton crop is made up of GM varieties.

In addition, there are a number of biotech cotton varieties currently undergoing trials, including those will the following modified traits: insect-resistance; herbicide-tolerance; fungal resistance; water use efficiency; water-logging tolerance; as well as a high oleic acid content variety (see Appendix II).

Australian food standards require approval and labeling of food or food ingredients that contain new genetic material or protein or have altered characteristics as a result of gene modification. Refined oil from biotech cottonseed, however, does not require a label because

the oil contains no genetic material and the cottonseed oil is identical to conventional cottonseed oil.

#### Canola

The commercial releases of two biotech canola varieties (InVigor® hybrid & Roundup Ready®) were approved by OGTR in 2003. However, commercial plantings of these varieties are being held up due to moratoriums that have been implemented by state governments in all Australia's major canola producing states (see Section IV of this report).

#### **Applications Under Evaluation**

A list of GMO applications currently under evaluation by OGTR is contained in Appendix I of this report.

#### **Imported Products**

Under the Gene Technology Act 2000, approval or authorization must be obtained to deal with genetically modified organisms. This means that the importation of live, viable GMOs, are regulated under the Act. Importers need to apply to OGTR for a license or authorization to import any GMO into Australia. OGTR and the Australian Quarantine and Inspection Service (AQIS) work closely to regulate and enforce this situation. The AQIS application form for an import permit contains a section relating to the genetically modified status of the product.

Foods containing biotech materials must be approved by Food Standards Australia New Zealand and be labeled if the biotech content is greater than 1% before they can be sold in Australia. This applies to all domestically produced and imported food. A list of currently approved biotech food products is contained in Appendix III of this report.

Processed animal feeds, such as soy meal, are not covered by biotech legislation in Australia. These products, therefore, do not require prior approval or a license (see Section III of this report) to be imported. There are, however, quarantine restrictions on some products. Unprocessed biotech products imported as feed (i.e. whole grain, etc), would require a license from OGTR, as there is a possibility that seed could be released into the environment.

#### Section III: Biotechnology Policy

#### The GMO Regulatory System

The Gene Technology Act 2000 (the Act) came into force on June 21, 2001 as the Commonwealth component of a national regulatory scheme. The Act and the associated Gene Technology Regulations 2001, provide a comprehensive process for the Gene Technology Regulator to assess proposed dealings with live and viable GMOs ranging from contained work in certified laboratories to general releases of GMOs into the environment, and extensive powers to monitor and enforce license conditions. An Inter-Governmental Agreement, between the Commonwealth and the states and territories, underpins the system for regulating genetically modified organisms in Australia. The Ministerial Council for Gene Technology, comprising ministers from the Commonwealth and each state and territory, oversees the regulatory framework and provides advice to the Gene Technology Regulator on policy principles to assist in decision-making. The individual states and territories have passed or are developing complimentary legislation to the Gene Technology Act in their jurisdictions.

The object of the Gene Technology Act is: "To protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with genetically modified organisms."

The Act prohibits all dealings with GMOs unless the dealing is:

- A licensed dealing;
- A notifiable low risk dealing;
- Exempt dealing; or
- Included on the GMO Register.

Key features of the Act are the appointment of an independent Gene Technology Regulator and a requirement for transparent and accountable implementation. The Regulator administers the regulation of all dealings with GMOs in Australia, in accordance with the Act and ensures compliance with the conditions of any approvals. The Regulator consults extensively with the community, research institutions and private enterprise.

The Gene Technology Regulator liaises with other regulatory agencies, including Food Standards Australia New Zealand (FSANZ), the National Registration Authority for Agricultural and Veterinary Chemicals (NRA), and the Therapeutic Goods Administration (TGA), to coordinate the approval of biotech products for use and sale. The Act creates a Public Record of GMO Dealings and GM Products that resides on the OGTR website: <a href="https://www.ogtr.gov.au">www.ogtr.gov.au</a>.

The Act also establishes three committees to advise the Regulator and the Ministerial Council:

- The Gene Technology Technical Advisory Committee (GTTAC) a group of highly qualified experts who provide scientific and technical advice on applications;
- The Gene Technology Ethics Committee (GTEC) a group of expert ethicists, which provides ethical advice, particularly in the areas of law, religious practices, animal welfare and population health; and
- The Gene Technology Community Consultative Committee (GTCCC) a group of people representing the broad interests within the Australian community, including consumers, researchers, and environmentalists. This group looks beyond the science of gene technology to matters of general concern to the community in relation to GMOs.

#### **GMOs vs GM Product**

The Gene Technology Act 2000 distinguishes between genetically modified organisms (GMOs) and genetically modified (GM) products. A genetically modified product - 'GM product' - means a thing (other than a GMO) derived or produced from a GMO (Section 10 of the GT Act).

The Office of the Gene Technology Regulator (OGTR) does not directly regulate the use of GM products in Australia. However, the use of GM products is regulated by other regulatory agencies in a number of situations. Food Standards Australia New Zealand (FSANZ) regulates the use of GM products in food for human consumption, and the Therapeutic Goods Administration regulates the use of GM products as human therapeutics. The National Industrial Chemical Notification and Assessment Scheme (NICNAS) regulates any GM products derived from industrial chemicals and the Australian Pesticides and Veterinary Medicines Authority (APVMA) evaluates and approves pesticides and veterinary medicines containing GM products.

#### **GMOs Already Licensed by OGTR**

A list of GMOs already licensed by OGTR is contained in Appendix II of this report.

#### **Biotech Food**

Food Standards Australia New Zealand (FSANZ) is the Australian Government agency responsible for approving GM food products for the Australian market. Mandatory labeling of genetically modified foods, where introduced DNA or protein is present in the final food, came into force in Australia on December 7, 2001. Regulations for labeling are contained in <a href="Standard 1.5.2">Standard 1.5.2</a> of the <a href="Food Standards Code">Food Standards Code</a>. A list of currently approved biotech food products is contained in <a href="Appendix III">Appendix III</a> of this report.

Under the Standard, food or ingredients labeled genetically modified contain new genetic material or protein as a result of the genetic modification or have altered characteristics, e.g. changed nutritional values, compared to the conventional food. Some flavorings may also be derived from genetically modified organisms, but labeling is only required if they are in a concentration of more than 1 gram per kilogram (0.1%). Food additives and processing aids do not need to be labeled unless the introduced genetic material is present in the final food.

Under the labeling standard, for packaged foods the words 'genetically modified' must be used in conjunction with the name of the food, or in association with the specific ingredient within the ingredient list; and for unpackaged foods for retail sale (such as unpackaged fruit and vegetables, or unpackaged processed or semi-processed foods) the words 'genetically modified' must be displayed in association with the food, or in association with the particular ingredient within that food.

#### **Biotech Feed Products**

Animal feeds containing GMOs (e.g. whole grains or oilseeds) are regulated by the OGTR. The OGTR considers any biosafety risks associated with the product and, if necessary, will apply special conditions, or may prohibit the use of the product as animal feed. As an example, after a GMO has undergone field trials, the organization conducting the trials may wish to use the unviable by-product (such as seed) as animal feed. Before the product is used in any way, the Gene Technology Regulator will consider any risks and, if necessary, will apply conditions or disallow the product to be used.

The Australian Quarantine & Inspection Service (AQIS) and the OGTR must approve genetically modified whole grain commodities (including oilseeds) imported into Australia for animal feed (such as whole soybeans and corn). The AQIS provides quarantine inspection and certification for the arrival of imports of the products to ensure the product is free of pest and disease and specific license conditions are enforced to ensure the product meets requirements. The OGTR also assesses the product, issues a license to the organization importing the product, and may apply further conditions above those stipulated by AQIS.

Large amounts of biotech feed products are used in Australia's intensive livestock sector. A large proportion of Australia's soybean meal is imported, including from the United States. All cottonseed meal used in Australia is considered to be biotech as over 80 percent of the cotton crop is planted to biotech varieties. Biotech and non-biotech cotton varieties are not typically segregated in Australia.

Genetically modified animal feed does not require special labeling in Australia.

#### Coexistence between Biotech & Non-Biotech Crops

Coexistence of biotech, conventional, and organic crops has occurred in Australia since biotech cotton varieties were commercially grown in 1996. As part of any license to grow a biotech crop, OGTR stipulates the conditions under which the crop can be grown to ensure no cross-contamination with conventional or organic crops in the vicinity.

In October 2005, national consensus was achieved in Australia regarding practical thresholds to deal with the issue of traces of GM canola in conventional canola consignments and variety trials. The Primary Industries Ministerial Council (PIMC), which is comprised of Ministers from the Australian Government and each state and territory, agreed upon adventitious presence (AP) thresholds for the presence of GM canola in conventional grain and seed.

The PIMC meeting agreed on two thresholds:

- An AP threshold of 0.9 per cent GM canola in canola grain. This is the threshold supported by the Australian Oilseeds Federation (AOF).
- A second threshold for AP of GM canola in seed was set at 0.5 per cent for 2006 and 2007, to be reduced to 0.1 per cent thereafter. The Australian Seed Federation (ASF) established an AP threshold of 0.5 per cent GM seed in non-GM planting seed in 2003 following two years of research and consultation with the canola seed industry.

A number of projects on GMO supply chain management have been undertaken as part of the Department of Agriculture, Fisheries & Forestry's Biotechnology Strategy for Agriculture, Fisheries and Forestry (BSAFF). These publications are available at: <a href="http://www.daff.gov.au/agriculture-food/biotechnology/project-reports/gm-non-gm">http://www.daff.gov.au/agriculture-food/biotechnology/project-reports/gm-non-gm</a>.

#### **Biosafety Protocol**

Australia has not signed or ratified the Biosafety Protocol and the Australian Government has no timetable for consideration of accession to the Protocol. This is due to concerns about how the Protocol will operate in practice (documentation requirements, and the liability and compliance arrangements are yet to be agreed), uncertainty about how parties will implement the Protocol and whether they will do so in a way which respects all of their international obligations, and uncertainty about any individual country's capacity to influence decision-making. Moreover, the government considers that the Protocol is not needed for Australia to manage biotech imports as Australia already has a robust regulatory framework through the Office of Gene Technology Regulator.

#### Section IV: Marketing

#### **Market Acceptance**

Australia has a substantial, risk assessment based regulatory framework for dealings with gene technology and genetically modified organisms and the Government is supportive of the technology for its agricultural producers and has been an ally of the United States with regard to the Cartagena Protocol on Biosafety (CPB). This comes despite anti-biotechnology activism in Australia that has promoted stringent labeling requirements and encouraged moratoria on biotechnology plantings. Australia's biotechnology sector is small in global terms, but growing, with over 420 biotechnology companies (this includes all types of biotechnology, not just agricultural biotechnology).

Major Australian commodity groups originally voiced concerns about introducing biotech canola and advocated for a 'go-slow' approach largely because of the potential impact biotech canola, which OGTR approved for commercial release in 2003, could have on their domestic and export businesses. In 2003 and 2004 several state governments (Victoria, NSW, South Australia, Western Australia, Tasmania and the ACT), using their powers over commodity 'marketing', imposed moratoria on the commercial release of products of biotechnology (with the exception of the previously approved cotton and carnations). The moratoria are all set to expire or be reviewed in 2008. Currently in Australia about 90 percent of the cotton planted is from biotech varieties, and there has been little controversy concerning its cultivation. Indeed, environmental benefits and the significant decline in pesticide and herbicide use for this crop have been widely reported. Biotech cottonseed does appear in the domestic market through the oil and meal, and this has not met with any major opposition.

In February 2006, The Agriculture and Food Policy Reference Group released its report, "Creating Our Future: Agriculture and Food Policy for the Next Generation" known as the Corish Report (see GAIN Report AS6013). This report was commissioned by the Agriculture Minister in March 2005 to help guide the development of future directions in Australian agricultural policies. On Biotechnology, one of the recommendations of the Corish Report was that State governments should lift their moratoriums on the commercial use of GM crops and work with the Australian Government, industry and researchers to achieve nationally consistent traceability and tolerance protocols, and to clarify legal liability surrounding the use of GM organisms in agriculture and food products.

In its response to the Corish Report in October 2006 (see GAIN report AS6062), the Federal Government agreed with this recommendation and indicated that it would continue to work with and encourage industry and state governments to address the issues in relation to marketing that led to the moratoriums on genetically modified (GM) products being imposed. The Government noted that the independent review of the Gene Technology Act 2000 also recommended that state governments should address the issues and re-evaluate the need for the moratoriums. The Government also indicated that it would also work with industry and interested state governments to develop appropriate arrangements to allow GM and non-GM producers to co-exist."

Australia's Agriculture Minister recently told a gathering of industry leaders and scientists that Australia's state and territory moratoria on genetically modified (GM) crops are placing Australia's agricultural sector at serious risk of being left behind by international competitors. The Minister welcomed the recent decisions by Victoria and Tasmania to review their GM crop bans and called on other jurisdictions to follow their lead. The Minister called for the states and territories to remove their moratoriums on GM crops to allow farmers to choose which crops they want to grow, and provide researchers and investors with a clear pathway to the marketplace.

The National Farmers Federation has also called on states to lift the moratoria on GM crops and the Victoria Farmers Federation recently voted in favor of sunsetting the moratorium on that state in February 2008 when it comes up for review.

An application to conduct the first Australian field trial of genetically modified (GM) wheat (modified for drought tolerance) has been given approval by the Gene Technology Regulator. The trial of the new GM wheat lines will take place at two sites in Victoria. Although AWB Limited, the monopoly wheat exporter, originally expressed concern about biotech wheat's potential impact on its existing export markets and argued that commercial releases should not go forward until market preferences change and/or the supply chain can guarantee segregation, they now indicate that they support the development of agricultural

biotechnology under controlled conditions because of the potential benefits to farmers and the environment. The company has indicated that it is supportive of plans to keep GM and non-GM products separate; the need to ensure there is no contamination that could endanger any markets; and the need to supply non-GM customers with non-GM wheat, even if GM wheat was grown commercially.

#### **National Biotechnology Strategy**

The Australian Federal Government launched the National Biotechnology Strategy (NBS) in July 2000 with A\$30.5 million over three years (FY 2001–04) for targeted initiatives to support the Government's vision for biotechnology. The Strategy was boosted in January 2001 by a further A\$66.5m from the Innovation Statement, Backing Australia's Ability, with funding for the Biotechnology Center of Excellence and additional funding for the Biotechnology Innovation Fund. In July 2004, under Backing Australia's Ability- Building Our Future through Science and Innovation, the Australian Government provided a further A\$20m to strengthen Australia's competitiveness in biotechnology, through continuing the National Biotechnology Strategy and Biotechnology Australia till 2008. Further funding was also provided to extend support for the Australian Stem Cell Centre until 2010-11.

Biotechnology also receives funding through other programs in the health, agriculture, environment and education portfolios. In addition to the Commonwealth Government's contribution to biotechnology development, Australia's State and Territory governments also commit resources to the development of biotechnology.

The key objective of the Strategy is to provide a framework for Government and key stakeholders to work together to ensure that developments in biotechnology are captured for the benefit of the Australian community, industry and the environment, while safeguarding human health and ensuring environmental protection. The Strategy addresses six key themes with specific objectives and strategies to achieve them:

- Biotechnology in the community
- Ensuring effective regulation
- Biotechnology in the economy
- Australian biotechnology in the global market
- Resources for biotechnology; and
- Maintaining momentum and coordination.

Following the 2004 BIO conference, a <u>National Approach Work Program</u> was agreed to by Australian Governments to build on national strengths in biotechnology collaboratively to avoid duplication and dilution of effort.

#### **Biotechnology Australia**

Biotechnology Australia (BA) was established in 1999 as an agency comprising five Australian Government departments - the Department of Industry, Tourism and Resources, the Department of Agriculture, Fisheries and Forestry, Department of Health and Ageing, Department of Environment and Heritage, and Department of Education, Science and Training. BA coordinates the non-regulatory biotechnology activities of the Australian Government. BA also works with the states and territories to strengthen national efforts on biotechnology through the Biotechnology Liaison Committee.

Biotechnology Australia and its partners have responsibility for managing the National Biotechnology Strategy.

Biotechnology Australia contains two sections (Strategic Policy, and Public Awareness) through which it undertakes a range of key activities, including:

- Management of the <u>National Biotechnology Strategy</u>
- Implementation of the Biotechnology National Approach Work Program
- A Public Awareness Program with multiple elements including:
  - The Gene Technology Information Service
  - Participation in rural and community forums
  - Provision of Educational Materials
  - Maintenance of the Biotechnology Online schools resource
  - Production of a Fact Sheets series
  - Extensive monitoring of Public Attitudes to Biotechnology
- Secretariat support for the <u>Biotechnology Ministerial Council</u>, the <u>Australian</u>
   <u>Biotechnology Advisory Council</u>, the <u>Biotechnology Liaison Committee</u>, and the
   meetings of Secretaries and officials from Biotechnology Australia's <u>partner agencies</u>.

#### **National Farmers Federation**

In March 2003, the National Farmers Federation released a <u>Biotechnology Position Statement</u> recognizing the potential of biotechnology as a valuable tool within agricultural production systems and urging that all potential benefits should be available to farmers to make informed choice in their farming decisions.

#### **Country Specific Studies Relevant to U.S. Exporters**

The **Department of Agriculture, Fisheries & Forestry** has a number of publications available on the <u>Agriculture & Food Biotechnology page</u>.

<u>Agrifood Awareness Australia</u> – This organization publishes a large number of bulletins and information guides.

<u>Rural Industries Research & Development Corporation</u> has published the following studies:

Impact of Genetic Engineering on Consumer Demand, February 2005 Global Response to GM Food Technology: Implications for Australia, February 2005

Biotechnology Australia also has a number of papers & reports available on their website.

#### Section V: Reference Material

Below are links to various organizations involved in the agricultural biotechnology sector in Australia.

Australian Government

Office of the Gene Technology Regulator

Biotechnology Australia

Food Standards Australia New Zealand

Australian Pesticides & Veterinary Medicines Authority

**Therapeutic Goods Administration** 

Department of Agriculture, Fisheries & Forestry

Other Organizations

Agrifood Awareness Australia

National Farmers Federation

## **Appendix I: GMO Applications Under Evaluation**

The Office of the Gene Technology Register has received the following applications for evaluation. All applications are posted on the OGTR website when they are first received and again when public comment is sought. Full details of all applications can be found at: <a href="http://www.ogtr.gov.au/ir/index.htm">http://www.ogtr.gov.au/ir/index.htm</a>

Product	Trait Category	Applicant	Status
Cotton	Limited and controlled release of GM herbicide tolerant and/or insect resistant Extra Long Staple (ELS) Cotton (Gossypium barbadense)	Monsanto Australia Ltd	Notification posted 16 May 2007
Cotton	Limited and controlled release of GM insect resistant and insect resistant/herbicide tolerant cotton	1 -	Notification posted 28 February 2007. Call for public comment posted 1 June 2007

#### Appendix II: GMOs Already Licensed for Use in Australia

The table below provides summary information about all Dealings for Intentional Release (DIRs) currently on the GMO Record (i.e. granted licenses for various uses). Full details of all applications can be found on the OGTR website at: <a href="http://www.ogtr.gov.au/gmorec/ir.htm">http://www.ogtr.gov.au/gmorec/ir.htm</a>

Crop	Applicant	Modified Trait	License Purpose	Status
Bread wheat Triticum aestivum L.	Department of Primary Industries - Victoria	Drought tolerance	Limited and Controlled Release of GM drought tolerant wheat	Current
Sugarcane Saccharum spp.	BSES Limited	Altered plant architecture, enhanced water or improved nitrogen use efficiency	Limited and Controlled Release of GM Sugarcane with altered plant architecture, enhanced water or improved nitrogen use efficiency	Current
Canola and Indian Mustard Brassica napus and Brassica juncea	Bayer CropScience Pty Ltd	Herbicide tolerance and hybrid breeding system	Limited and controlled release of GM herbicide tolerant hybrid Brassica napus and hybrid Brassica juncea	Current
Torenia cv. "Summerwave®"  Torenia X hybrida	Florigene Pty Ltd	Altered flower colour (flavonoid biosynthesis)	Limited and Controlled Release of Genetically Modified (GM) Torenia with altered flower colour	Current
Cotton Gossypium hirsutum L	CSIRO	Waterlogging tolerance	Limited and Controlled Release of Waterlogging Tolerant (GM) Cotton	Current
Cotton Gossypium hirsutum L	Monsanto Australia Pty Ltd	herbicide tolerant and/or insect resistant	Commercial Release of GM herbicide tolerant and/or insect resistant cotton lines north of latitude 22° South	Current
Cotton Gossypium hirsutum L	Deltapine Australia Pty Ltd	Insect resistance	Limited and Controlled Release of Insect Resistant Genetically Modified Cotton	Post-harvest monitoring

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Gossypium hirsutum L	Monsanto Australia Ltd	Water-use efficiency	Limited and Controlled Release of Water-Efficient Genetically Modified Cotton	Current
Cotton Gossypium hirsutum L	Hexima Ltd	Fungal resistance	Field trial of GM cotton expressing natural plant genes for fungal control	Post-harvest monitoring
Cotton Gossypium hirsutum L	Bayer CropScience Pty Ltd	Herbicide tolerance	Commercial release of herbicide tolerant Liberty Link® Cotton	Current
Rose Rosa X hybrida L	Florigene Limited	Altered flower colour, selectable marker	Limited and controlled release of GM rose lines	Current
Cotton Gossypium hirsutum L	Monsanto Australia Pty Ltd	Prolonged herbicide tolerance and/or insect resistance, antibiotic resistance, reporter gene expression	Commercial release of herbicide tolerant (Roundup Ready Flex® MON 88913) and herbicide tolerant/insect resistant (Roundup Ready Flex® MON 88913/Bollgard II®) cotton south of latitude 22° South in Australia	Current
Indian mustard (includes Brown and Oriental mustard) Brassica juncea L. Czern and Coss.	Bayer CropScience Pty Ltd	Herbicide tolerance and hybrid breeding system	Field trials of genetically modified herbicide tolerant, hybrid Brassica juncea	Post-harvest monitoring
Cotton Gossypium hirsutum L	Bayer CropScience Pty Ltd	Herbicide tolerance, insecticidal action, antibiotic resistance, reporter gene expression	Field trial of herbicide tolerant (LLCotton25)and herbicide tolerant/insect resistant (LLCotton25/Bollgard II®) cottons	Current/Post- harvest monitoring
Bread wheat Triticum aestivum L	CSIRO	Altered grain starch and Antibiotic resistance	Field trial of genetically modified wheat with altered grain starch	Post-harvest monitoring

Cultivated rice Oryza sativa L. cv Nipponbare	CSIRO	Herbicide tolerance, antibiotic resistance and reporter genes have been randomly inserted into rice plants. Some plant growth traits may be modified by gene knockouts.	Field trial of genetically modified rice ( <i>Oryza sativa</i> L.) functional characterisation of the rice genome	Post-harvest monitoring
Sugarcane Saccharum officinarum L. x S. spontaneum L.	The University of Queensland	Altered sugar production and Antibiotic resistance	Field trial of genetically modified (GM) sugarcane expressing sucrose isomerase	Current
Bovine herpesvirus 1 (BoHV-1) Bovine herpesvirus 1 subtype 1.2b strain V155	Queensland Department of Primary Industries & Fisheries	expression of green fluorescent protein (GFP)     expression of envelope glycoprotein E2     expression of a truncated E0 glycoprotein fused to GFP or to the E2 glycoprotein     localisation of introduced proteins on the surface of the GMOs or host cells     deletion or disruption of endogenous BoHV-1 genes	Vaccination of cattle with recombinant bovine herpesvirus vaccines	Current
Cotton Gossypium hirsutum L	Hexima Limited Ltd	Insecticidal action, antibiotic resistance	Field trial to assess transgenic cotton expressing natural plant genes for insect control	Post-harvest monitoring
White Clover Trifolium repens L	Department of Primary Industries (Victoria)	Viral Disease Resistance, Antibiotic resistance	Field Evaluation of Genetically Modified White Clover Resistant to Infection by Alfalfa Mosaic Virus	Current/Post - harvest monitoring
Fowl adenovirus Fowl adenovirus, serotype 8, isolate CFA44	Imugene Limited	Immunomodulatory protein expression, Attenuation	Limited and controlled release of GM fowl adenovirus (FAV)	Current

Cotton	Dow	Insecticidal and	Agronomic	Current/Post-
Gossypium hirsutum L	AgroSciences Australia Pty Ltd	herbicide tolerance	assessment and seed increase of transgenic cottons expressing insecticidal genes (cry1Ac and cry1Fa) from Bacillus thuringiensis	harvest monitoring
Gossypium hirsutum	CSIRO	Modified fatty acid content in cottonseed oil	Field Evaluation of Genetically Modified High Oleic (HO) Cotton	Post-harvest monitoring
Cotton Gossypium hirsutum	Syngenta Seeds Pty Ltd	Insect resistance, antibiotic resistance	The Evaluation of Transgenic Cotton Plants Expressing the VIP Gene	Current
Cholera vaccine Vibrio cholerae	CSL Ltd	Attenuation by removal of cholera toxin subunit A and inclusion of a mercury resistance marker	Commercial release of recombinant live oral cholera vaccine (Orochol® vaccine)	Current
Canola Brassica napus	Bayer CropScience Pty Ltd	herbicide tolerant hybrid canola	Field Trial - Seed increase and field evaluation of herbicide tolerant hybrid canola	Current/Post- harvest monitoring
Grapevines Vitis vinifera L.	CSIRO	Expression of modified colour, sugar composition, flowering and fruit development, expression of green fluorescence protein, antibiotic resistance	Field trial of GM grapevines - Evaluation of berry colour, sugar composition, flower and fruit development and gene flow study	Current
Pineapple Ananas comosus	Department of Primary Industries	Reduction of blackheart, delayed flowering, reporter gene expression, antibiotic resistance	Field trial of pineapple plants modified for blackheart reduction and to delay flowering	Current
<b>Papaya</b> Carica papaya	The University of Queensland	Delayed fruit ripening, reporter gene expression and antibiotic resistance	Field trial for evaluation of GM papaya to delay fruit ripening and to test the expression of the introduced genes	Post-harvest monitoring

Cotton Gossypium hirsutum	Monsanto Australia Ltd	Herbicide tolerant, insecticidal cotton	Commercial release of herbicide tolerant (Roundup Ready®) and herbicide tolerant/insect resistant (Roundup Ready®/INGARD®) cotton	Current
Cotton Gossypium hirsutum	Monsanto Australia Ltd	Insecticidal cotton	Commercial release of insecticidal (INGARD®) cotton	Current
Canola Brassica napus	Bayer CropScience Pty Ltd	Herbicide tolerance, Hybrid Breeding System	Commercial release of InVigor® hybrid canola (Brassica napus) for use in the Australian cropping system	Current
Canola Brassica napus	Monsanto Australia Ltd	Herbicide tolerance	General release of Roundup Ready® canola (Brassica napus) in Australia	Current
Sugarcane Saccharum interspecific hybrid	Bureau of Sugar Experiment Stations	Green fluorescent reporter gene	Agronomic assessment of transgenic sugarcane engineered with reporter genes	Post-harvest monitoring
Cotton Gossypium hirsutum	CSIRO	Insect resistance	Field trials of insect resistant cotton	Post-harvest monitoring
Cotton Gossypium hirsutum	Monsanto Australia Ltd	Insect resistance and herbicide tolerance	Commercial release of BollgardII and BollgardII/Roundup Ready® cotton	Current/Post- harvest monitoring
Canola Brassica napus	Aventis CropScience Pty Ltd	Hybrid breeding system and herbicide tolerance	Small and large scale trialing of InVigor® canola (Brassica napus) for development for the Australian cropping system	Post-harvest monitoring

## **Appendix III: Approved GM Food Products**

The following table contains a current list of approved biotech food products. Detailed information is contained in <u>Standard 1.5.2</u> on the FSANZ web site.

Food produced using gene technology	Special conditions
Food derived from glufosinate ammonium- tolerant corn line T25 Food derived from glufosinate ammonium tolerant cotton line LL25 Food derived from glufosinate ammonium tolerant soybean lines A2704-12 and A5547-127	
Food derived from glyphosate-tolerant corn line GA21 Food derived from glyphosate-tolerant corn	
line NK603  Food derived from glyphosate-tolerant cotton line MON 88913  Food derived from glyphosate-tolerant lucerne J101 and J163	
Food derived from glyphosate-tolerant soybean line 40-3-2 Food derived from glyphosate-tolerant sugarbeet line 77	
Food derived from high oleic acid soybean lines G94-1, G94-19 and G168	The label on or attached to a package of a food derived from high oleic acid soy bean lines G94-1, G94-19 and G168 must include a statement to the effect that the food has been genetically modified to contain high levels of oleic acid
Food derived from insect- and potato leafroll virus-protected potato lines RBMT21-129, RBMT21-350, and RBMT22-82. Food derived from insect- and potato virus Y-	g
protected potato lines RBMT15-101, SEM15-02 and SEM15-15. Food derived from insect-protected and	
glufosinate-ammonium tolerant corn line 1507	
Food derived from insect-protected and glufosinate ammonium-tolerant DBT418 corn	
Food derived from insect-protected and glyphosate-tolerant corn line MON88017	
Food derived from insect-protected Bt - 176 corn.  Food derived from insect-protected corn	
event MON863 Food derived from insect-protected corn line	
MIR604 Food derived from insect-protected corn line MON 810	

Food derived from insect-protected, glufosinate ammonium-tolerant Bt-11 corn. Food derived from insect-protected, glufosinate ammonium-tolerant corn line DAS-59122-7

Food derived from insect-protected potato lines BT-06, ATBT04-06, ATBT04-31, ATBT04-36, and SPBT02-05

Food derived from sugar beet line H7-1 Oil and linters derived from bromoxyniltolerant cotton containing transformation events 10211 and 10222

Oil and linters derived from glyphosatetolerant cotton line 1445

Oil and linters derived from insect-protected cotton line COT102

Oil and linters derived from insect-protected cotton lines containing event 15985

Oil and linters derived from insect-protected cotton lines 531, 757 and 1076

Oil and linters derived from insect-protected, glufosinate ammonium-tolerant cotton line MXB-13

Oil derived from bromoxynil-tolerant canola line Westar-Oxy-235

Oil derived from glufosinate-ammonium tolerant canola lines Topas 19/2 and T45 and glufosinate-ammonium tolerant and pollination controlled canola lines Ms1, Ms8, Rf1, Rf2 and Rf3

Oil derived from glyphosate-tolerant canola line GT73

## **Recent Reports from FAS/Canberra**

The reports listed below can all be downloaded from the FAS website at: <a href="http://www.fas.usda.gov/scriptsw/AttacheRep/default.asp">http://www.fas.usda.gov/scriptsw/AttacheRep/default.asp</a>.

Report Number	Title of Report	Date
AS7035	Ag Down Under Vol. 7, 2007	06/22/07
AS7034	Parliament Passes Legislation to Amend Wheat Marketing in	06/22/07
	Australia	
AS7033	"Australian Grown" Logo Launched	06/22/07
AS7032	Biofuels Annual	06/08/07
AS7030	Dairy Semi-Annual	05/17/07
AS7029	Soybeans Approved for Import	05/14/07
AS7028	Ag DownUnder Vol. 6, 2007	05/11/07
AS7026	Cotton Annual	04/26/07
AS7025	Senate To Hold Inquiry Into NZ Apple Decision	04/19/07
AS7024	AWB Shareholders Sue for A\$25m	04/18/07
AS7023	Ag DownUnder Vol. 5, 2007	04/13/07
AS7021	Additional Comments Sought on Nutrition & Health Claims Standard	04/11/07
AS7020	Sugar Annual	04/10/07
AS7018	Ag Down Under Vol. 4	03/27/07
AS7017	Biosecurity Policy Determination - Importation of Apples from New Zealand	03/27/07
AS7016	Grain and Feed Annual	03/27/07
AS7014	Stone Fruit Annual	03/16/07
AS7012	Ag DownUnder Vol. 3, 2007	03/09/07
AS7009	Cotton Quarterly Lockup Report	02/27/07
AS7008	Import Risk Analysis Report for Apples from New Zealand	02/27/07
AS7007	Ag DownUnder Vol. 2, 2007	02/23/07
AS7006	Livestock Semi-Annual	02/20/07
AS7005	Ag DownUnder Vol. 1, 2007	02/02/07
AS7004	Grain Quarterly Update	01/25/07
AS7003	Tree Nuts Annual	01/11/07
AS7002	Promotion Opportunities Report	01/09/07
AS7001	Fresh Deciduous Fruit Annual	12/20/06